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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,760	01/03/2002	Brett Finlay	9003-0001	9198
23419	7590	03/05/2004		
COOLEY GODWARD, LLP 3000 EL CAMINO REAL 5 PALO ALTO SQUARE PALO ALTO, CA 94306				EXAMINER SHAHNAN SHAH, KHATOL S
				ART UNIT 1645 PAPER NUMBER

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/039,760	FINLAY ET AL.
<b>Examiner</b>	<b>Art Unit</b>	
Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 08 December 2003.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 33-62 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 33-62 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/20/2002.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

***DETAILED ACTION***

1. Applicants' amendment, received December 08, 2003 is acknowledged. Claims 1-32 have been canceled. New claims 35-62 have been added.

***Election/Restrictions***

2. Applicants' election without traverse of December 08, 2003 is acknowledged. Applicants elected group III claims 33-34 which are drawn to a method for reducing colonization of enterohemorrhagic E.coli in a mammal. Newly added claims 35-62 will be examined under elected group III.
3. Currently claims 33-62 are pending and under consideration.

***Information Disclosure Statement***

4. Applicants' Information disclosure statement, received 9/20/2002 is acknowledged.

The references have been considered by the Examiner (see attached PTO form 1449).

***Specification***

5. The disclosure is objected to because of the following informalities:

The use of the trademark VSA3 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 33-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing colonization or shedding of EHEC in bovine and ovis species, does not reasonably provide enablement for a method of reducing colonization or shedding of EHEC in all mammals including humans. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/and or use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

In the instant case claims are broadly drawn to a method of reducing colonization of EHEC in all mammals including humans. The specification is only enabled for a method reducing colonization of EHEC in certain ruminants such as cows and sheep. The given examples in the specification, examples 4 and 5 are directed to monitoring shedding and colonization of EHEC in cattle. It is well known in the art that the cattle are an important reservoir and are carriers of EHEC while in humans EHEC is an important pathogen causing diarrhea with life threatening complications.

Applying the above test to the facts of record, it is determined that 1) insufficient direction or guidance is presented in the specification with respect to a method having claimed functional feature of capability of reducing colonization or generating protective responses in all mammals including humans, 2) there are no working examples which suggest the desired results of protecting against EHEC, 3) the nature of the invention involved the complex and incompletely understood area of protective immune responses against EHEC, 4) the state of the prior art shows the lack of correlates to immunity with EHEC specially in humans, 5) the relative skill of those in the art is commonly recognized as quite high (post – doctoral level).

In view of all of the above, in view of the lack of predictability in the art, and lack of guidance on how to obtain the desired effect using the claimed vaccine complex it is determined that it would require undue experimentation to make and/or use the claimed invention commensurate in scope with the claims.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 33-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites the limitation "said ruminant" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 34 recites the limitation "said ruminant" in line 2. There is insufficient antecedent basis for this limitation in the claim.

The term "about" in claims 43, 44, 57 and 58 is a relative term, which renders the claim indefinite. The term "about" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

It is not clear what constitute the metes and bounds of the term "at least" in claims 46, 48, 60 and 62.

Claims 45-48 and 59-62 are indefinite because they contain the abbreviations Tir, EspA, EspB and EspD. Full terminology should be in each instance in the claims without the additional use of redundant abbreviations in parentheses or otherwise. Correction is required.

The use of the trademark VSA3 has been noted in claims 42-44 and 56-58. It should be capitalized wherever it appears and be accompanied by the generic terminology.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 33- 36, 38, 45, 49, 50 and 59 are rejected under 35 U.S.C. 102(a) as being anticipated by Li et al. (Infection and Immunity Vol. 68, No.9, pp. 5090-5095, September 2000).

The claims are drawn to a method of reducing colonization of enterohemorrhagic E. coli (EHEC) in a mammal comprising administering a composition comprising an EHEC cell culture supernatant.

Li et al. teach a method of reducing colonization of enterohemorrhagic E. coli (EHEC) in a mammal comprising administering a composition comprising an EHEC cell culture supernatant (see abstract, pages 5090-5091). Li et al. teach reducing colonization in cattle (page 5090), EHEC 0157:H7, Tir, intimin, EsPA, EspB (see pages 5090-5091). The prior art teach the claimed invention.

***Claim Rejections - 35 USC § 103***

**12.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**13.** Claims 33-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (Infection and Immunity Vol. 68, No.9, pp. 5090-5095, September 2000) as applied to claims 33- 36, 38, 45, 49, 50 and 59 above, and further in view of Little-van den Hurk et al. (US 5,951,988). Prior art of the record.

The claims are drawn to a method of reducing colonization of enterohemorrhagic E. coli (EHEC) in a mammal comprising administering a composition comprising an EHEC cell culture supernatant.

Li et al. teach a method of reducing colonization of enterohemorrhagic E. coli (EHEC) in a mammal comprising administering a composition comprising an EHEC cell culture supernatant (see abstract, pages 5090-5091). Li et al. teach reducing colonization in cattle (page 5090), EHEC 0157:H7, Tir, intimin, EsPA, EspB (see pages 5090-5091). Li et al. do not teach

adjuvants such as VSA3. However, Little-van den Hurk et al. teach adjuvant formulations such as an oil-in-water emulsion (see abstract), DDA (see column 6) and VSA3 (see example 7).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the methods of Little-van den Hurk et al. and Li et al. to obtain the claimed invention. One of ordinary skill in the art would have been motivated to use the adjuvants of Little-van den Hurk et al, with the expectation of obtaining a composition with enhanced immunogenic activity. The criticality of the recited amounts of the components of the composition has not been established and would be a matter of design choice. Limitations such as different concentrations are being viewed as limitations of optimizing experimental parameters.

### ***Conclusion***

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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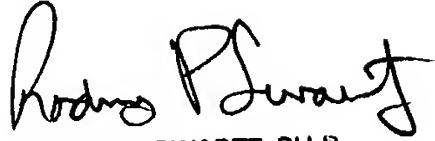
system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Khatol Shahnan-Shah, BS, Pharm, MS  
Biotechnology Patent Examiner

Art Unit 1645

March 2, 2004



RODNEY P. SWARTZ, PH.D  
PRIMARY EXAMINER